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9. 510 (k) SUMMARY

Submitted By:
Thomas J. Kardos
Vice President, Regulatory Affairs
Cook Vascular Incorporated
P.O. Box 529
Route 66, River Road
Leechburg, PA 15656
724-845-8621
February 5, 2002

Device:

Trade Name:	Cook Vascular Peel-Away® Introducer Valve
Common/Usual Name:	Introducer Valve, Hemostasis Valve
Proposed Classification Name:	Introducer, Catheter 21 CFR Part 870.1340 (74-DYB)

Predicate Devices:
The Cook Vascular Peel-Away® Introducer Valve is similar to predicate vascular introducer valves with respect to intended use, material composition, and method of operation.

Device Description:
The Cook Vascular Peel-Away® Introducer Valve is an Introducer Accessory placed on the proximal end of an introducer, intended to minimize the loss of blood during the introduction of cardiac heart leads, angiographic catheters and similar devices into the vascular system. The available side-port model allows flushing of the introducer as needed. The Cook Vascular Peel-Away® Introducer Valve is supplied sterile and intended for one time use.

Substantial Equivalence:
The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Vascular Incorporated. This device is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510 (k) substantial equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas J. Kardos
Vice President, Regulatory Affairs
Cook Vascular Incorporated
P.O. Box 529
Route 66, River Road
Leechburg, PA 15656

APR 2 5 2002

Re: K010128
Cook Vascular Peel-Away® Introducer Valve
Regulation Number: 870.1340
Regulation Name: Catheter intoducer
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: February 5, 2002
Received: February 7, 2002

Dear Mr. Kardos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010128

Device Name: Cook Vascular Peel-Away® Introducer Valve

Indications For Use:

The Peel-Away® Introducer Valve is intended to minimize the loss of blood during the introduction of cardiac heart leads, angiographic catheters and similar devices into the vascular system.

The Peel-Away® Introducer Valve is supplied sterile and intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010128

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)